

**REMARKS/ARGUMENTS**

A final Office Action was mailed on February 7, 2007. Applicants timely filed an Amendment in Response to the final Office Action on July 9, 2007, together with a Petition for a two-month extension of time. An Advisory Action was mailed on August 3, 2007, indicating that the Amendment of July 9, 2007 would not be entered as the proposed claim amendments introduced new features requiring further search and consideration. Applicants timely filed a Notice of Appeal on August 6, 2007 together with a Petition for a three-month extension of time, and timely file this Preliminary Amendment together with a Request for Continued Examination (RCE) and Petition for a one-month extension of time.

Reconsideration of this application is respectfully requested.

**I. Status of the Application**

Claims 204 - 253 are pending, with claims 1 - 203 having been previously canceled. Applicant cancels claims 207, 213, 242 and 248 - 253 without prejudice or disclaimer, and amends claims 204 - 206, 209, 210, 214 - 217, 222, 223, 226- 229, 238, 239, 241, 244 and 245 to provide improved clarity and consistency among related claims. No new matter is introduced. Support for the amendments may be found, for example, with reference to Applicant's specification at page 2, line 29 - page 3, line 1, page 4, line 34 - page 5, line 33, page 7, line 18 - page 8, line 8, and to Applicant's FIGs. 2 and 3(a) - 3(f).

**II. Claim Rejections under 35 U.S.C. §§ 102, 103**

Claims 204 - 209, 215 - 221, 224 - 229, 231 - 236, and 239 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Publication 2002/0002474 to Michelson et al. Claims 210 - 214, 222, 223, 237, 238 and 245 - 253 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michelson in view of "drkoop.com & Quintiles Launches Service to Recruit  
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Clinical Trial Patients on the Internet,” PR Newswire, June 28, 1999 (“Newswire”). Claims 230 and 240 - 244 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michelson in view of U.S. Patent No. 6,171,112 to Clark (“Clark”). As claims 207, 213, 242 and 248 - 253 have been canceled without prejudice or disclaimer, Applicant submits that the rejections as to claims 207, 213, 242 and 248 - 253 are moot. Applicant amends claims 204 - 206, 209, 210, 214 - 217, 222, 223, 226- 229, 238, 239, 241, 244 and 245 to further clarify the nature of his invention, and respectfully traverses the rejections of claims 204 - 206, 208 - 212, 214 - 241, and 243 - 247 under 35 U.S.C. §§ 102, 103. In particular, Applicant asserts that the Michelson and Newswire references must be disqualified as prior art references in the rejections under 35 U.S.C. §§ 102, 103, as Applicant’s invention as claimed was conceived and reduced to practice before the effective dates of these references.

The following timeline and the detailed discussion<sup>1</sup> that follows are provided in support Applicant’s assertion.

### **Timeline**

#### **No later than May 24, 1999**

Applicant makes at least the following pages accessible to members of the public as a mechanism for volunteering to be considered as participants in clinical trials, headlined as follows, and begins collecting registrations:<sup>2</sup>

[http://www.thebody.com/surveys/health\\_survey.html](http://www.thebody.com/surveys/health_survey.html) “Volunteer for Research!”<sup>3</sup>

[http://www.thebody.com/surveys/health\\_survey1.html](http://www.thebody.com/surveys/health_survey1.html) “Volunteer for Research!/Participation Agreement”<sup>4</sup>

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<sup>1</sup> Supported by Declarations by James D. Marks, Bonnie Goldman, Dahlia Elsayed, Jason K. Dewey and Christopher Andrews as identified in the Detailed Discussion.

<sup>2</sup> Exhibit C, 1<sup>st</sup> Goldman Declaration

<sup>3</sup> Exhibits G, I, Andrews Declaration (*two separate backups of this file, dated 5/24/99*); Exhibit Q, 2<sup>nd</sup> Goldman<sup>6</sup> Declaration (*capture with graphics by archive.org dated 10/2/99*).

<sup>4</sup> Exhibits H, J, Andrews Declaration (*two separate backups of this file, dated 5/24/99, with headline “Volunteer for Research! Participation Agreement”*); Exhibit R, 2<sup>nd</sup> Goldman Declaration (*capture with graphics by archive.org dated 7/12/2000, with revised headline “Applying for Clinical Studies and Research/Participation Agreement”*).

[http://www.thebody.com/surveys/health\\_survey2a.ihtml](http://www.thebody.com/surveys/health_survey2a.ihtml) "Health Survey"<sup>5</sup>

[http://www.thebody.com/surveys/health\\_remove.ihtml](http://www.thebody.com/surveys/health_remove.ihtml) "Removing Your Name from *The Body's* List of Volunteers for Research"<sup>6</sup>

### **June 28, 1999**

Dr.Koop.com and Quintiles transmit a press release via Newswire ("Newswire").

### **On or about September 1,1999**

Applicant begins collecting registrations of physicians interested in serving as clinical researchers of investigative drugs, at the following page.

<http://www.thebody.com/surveys/physicians.html> "Research Opportunities for Physicians"<sup>7</sup>

### **September 2, 1999**

U.S. Postal Service (USPS) post mark date on first physician post card sent to Applicant in response to Applicant's promotion of the "Research for Physicians" page.<sup>8</sup>

### **January 28, 2000**

Michelson files Provisional Patent Application No. 60/178,634 ("the '634 Application") with the U.S. Patent & Trademark Office (USPTO).

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<sup>5</sup> Exhibit L, 2nd Marks Declaration, beginning at page 8.

<sup>6</sup> Exhibit P, 2<sup>nd</sup> Goldman Declaration (*capture with graphics by archive.org dated 9/12/99*); Exhibits C-F, Andrews Declaration (*source code from two separate backups of each of two files all dated 5/24/99, showing links from two web site pages to [http://www.thebody.com/surveys/health\\_remove.ihtml](http://www.thebody.com/surveys/health_remove.ihtml)*).

<sup>7</sup> Exhibit M, 2<sup>nd</sup> Marks Declaration (*capture with graphics by archive.org dated 1/18/2000*).

<sup>8</sup> Exhibit O, 2<sup>nd</sup> Marks Declaration.

**April 21, 2000**

Applicant files the present application with USPTO.

**January 29, 2001**

Michelson files International Application No. PCT/US1/02936.

**August 8, 2001**

Michelson files U.S. Patent Application No. 09/923,385 with the USPTO.

As shown by the above timeline, no later than May 24, 1999, Applicant made accessible to members of the public the pages with the headlines “Volunteer for Research!,” “Volunteer for Research!/Participation Agreement,” “Health Survey,” and “Removing Your Name from *The Body’s* List of Volunteers for Research,” as mechanisms enabling members of the public to self-enroll be considered as participants in clinical trials and to withdraw from participation if so desired. The pages were in all in good working order and resulted in collection of personally identifying information and medical data from actual volunteers as early as **May 24, 1999**, well in advance of the publication of Newswire on June 28, 1999 and the earliest U.S. patent application filing by Michelson (the ‘634 Application) on January 28, 2000. Applicant made accessible to physicians the page “Research Opportunities for Physicians” as a mechanism for enrolling clinical researchers on or about September 1, 1999, and received at least one physician enrollment by **September 2, 1999**, well in advance of the filing of Michelson’s ‘634 Application on January 28, 2000.

A more detailed discussion follows, introducing Declarations by James D. Marks, Bonnie Goldman, Dahlia Elsayed, Jason K. Dewey and Christopher Andrews that provide evidence in support of the above-presented timeline.



(Exhibit 6) and a Declaration of Christopher Andrews (Exhibit 7) are also enclosed with this Response, together with copies of associated Exhibits A - J and L - R.

Applicant asserts that the Declarations and associated Exhibits together establish that the invention as completed prior to **May 24, 1999** embodied at least the following claim elements:

- A method for on-line recruitment of individuals wishing to volunteer for consideration as potential candidates for participating as research subjects in a plurality of clinical trials (see, e.g., Declaration of Marks and the second Declaration of Marks).
- A server of a recruitment service provider for transmitting a health survey to an end-user terminal for gathering an individual's contact information and at least one of the individual's personal or medical information (see, e.g., Declaration of Marks, the second Declaration of Marks and associated Exhibit L, the second Declaration of Goldman and the Declaration of Andrews and associated Exhibits G - J).
- The server storing the health survey information securely in a database (see, e.g., Declarations of Goldman, Elsayed and Dewey).
- Comparing stored survey information to clinical trial selection criteria to identify potential candidates (see, e.g., Declarations of Goldman, Elsayed and Dewey).
- The server transmitting a participation agreement to the end-user terminal, and requiring assent to the participation agreement as a requirement for accepting and storing the health survey information. (see, e.g., Declarations of Marks and Goldman, the second Declaration of Marks, the second Declaration of Goldman and associated Exhibit R, and the Declaration of Andrews and associated Exhibits G - J).







